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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,407	01/17/2006	Laurent Meijer	040388-0131	4591

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EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,407	MEIJER ET AL.	
	Examiner	Art Unit	
	Laura Schuberg	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/02/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowenheim (WO 99/42088).

Claim 1 is drawn to a method for treating deafness in a subject comprising administering a pharmaceutical composition that comprises at least one kinase inhibitor or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier, in an amount effective for inducing differentiation of supernumerary hair cells and Deiters' cells in an organ of Corti.

Claim 4 includes wherein the kinase inhibitor is administered parenterally, rectally, topically, transdermally, or orally.

Lowenheim teaches a method of treating deafness that uses local application of kinase inhibitors in a pharmaceutically acceptable carrier (page 11) for inducing

differentiation of supernumerary hair cells and Deiters' cells in an organ of Corti (page 5) (claims 1 and 4).

Therefore, Lowenheim anticipates Applicant's invention as claimed.

Claims 1, 4-9, 11, 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al (US 2002/0151491 A1).

Claim 5 includes wherein the kinase inhibitors are administered by oral or injectable route.

Claim 6 includes different forms of the kinase inhibitor.

Claim 7 includes wherein the composition comprises 100-1000 mg of the kinase inhibitor per dose unit.

Claim 8 includes wherein the kinase inhibitor is administered in various forms.

Claim 9 includes wherein the injectable solution comprises 100-1000 mg of the kinase inhibitor or salt.

Claim 11 includes wherein the composition comprises 300-600 mg of the kinase inhibitor or salt per dose unit.

Claim 12 includes wherein the injectable solution comprises 300-600 mg of the kinase inhibitor or salt.

Li teaches a method for treating hearing loss that uses administration of a kinase inhibitor (page 5 para 42) (claim 1). Methods of administration include locally, orally, intravenously, intramuscularly, or intranasally (page 6 para 50) (claims 4, 5, 8). The dosage of the protein components is taught to vary with the method of administration

and the severity of condition. The dosage for systemic administration is taught to include 300 mg/ml and 500 mg/ml per dose unit (page 6 para 53)(claims 7, 9, 11, 12). Li also teaches wherein the kinase inhibitors are in the form of drops, oral formulations and injectable solutions (page 6 para 50) (claims 6 and 8). A pharmaceutically acceptable carrier is also included (page 6 para 54) (claim 1).

While the reference is silent to the effect the kinase inhibitors have for inducing differentiation of supernumerary hair cells and Deiters' cells in an organ of Corti, this is deemed to be an inherent effect of the method since the reference is using the claimed composition in the claimed amount. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition or method, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

Therefore, Li inherently anticipates Applicant's invention as claimed.

Claims 1, 4-9, 11, 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Nicotera et al (US 2004/0019015 A1).

Nicotera teaches a method of treating hearing loss with protein kinase inhibitors that can be administered orally, parenterally, subcutaneously, intravenously, intramuscularly and includes a pharmaceutically acceptable carrier in solid or liquid form, such as tablets, capsules, solutions, suspensions or emulsions (page 8 para 70).

The dosage is taught to vary, but may include from about 50 mg to 1000 mg/kg of protein kinase inhibitor, preferably 50-400 mg/kg (page 8 para 74).

While the reference is silent to the effect the kinase inhibitors have for inducing differentiation of supernumerary hair cells and Deiters' cells in an organ of Corti, this is deemed to be an inherent effect of the method since the reference is using the claimed composition in the claimed amount. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition or method, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.

Therefore, Nicotera inherently anticipates Applicant's invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meijer (WO 01/41768 A2) in view of Nicotera et al (US 2004/0019015 A1) and Schaefer et al (US 6,096,873).

Claim 2 includes wherein the kinase inhibitor is a purine derivative.

Claim 3 includes wherein the purine derivative is selected from roscovitine, indirubin and purvalanol.

Claim 13 includes wherein the salt is an acid addition salt.

Claim 14 includes wherein the acid is selected from a group.

Meijer teaches a method of treating neurodegenerative disorders that includes the administration of a protein kinase inhibitor such as roscovitine, purvalanol, or indirubin (page 1 lines 21-23, page 3 line 22). The addition of a pharmaceutically acceptable carrier and acid addition salts such as acetic, ascorbic, maleic, phosphoric, salicylic and tartaric are taught as well as administration in various forms such as parenterally, rectally, topically, transdermally or orally (including injectable) (page 4 lines 15-30). For administration by the oral route, lozenges, compressed tablets, pills, tablets,

capsules, drops, syrups, suspensions or emulsions may be used with the composition comprising 100-1000 mg of active principle per dose unit, preferably 300-600 mg (page 5 lines 1-4). Other forms of administration include intravenous, subcutaneous or intramuscular route, formulated from sterile or sterilizable solutions and from suspensions and emulsions (page 5 lines 6-8).

Meijer does not specifically teach that hearing loss caused by nerve damage is a neurodegenerative disorder and thus treatable by the reference method.

Nicotera teaches a method of treating hearing loss with protein kinase inhibitors that can be administered orally, parenterally, subcutaneously, intravenously, intramuscularly and includes a pharmaceutically acceptable carrier in solid or liquid form, such as tablets, capsules, solutions, suspensions or emulsions (page 8 para 70). The dosage is taught to vary, but may include from about 50 mg to 1000 mg/kg of protein kinase inhibitor, preferably 50-400 mg/kg (page 8 para 74).

Schaefer teaches that neurodegenerative disorders include nerve deafness (column 24 line 67-column 25 line 3).

Therefore, one of ordinary skill in the art would have been motivated to use the method of Meijer to treat hearing loss caused by nerve damage because Schaefer teaches that neurodegenerative disorders include nerve deafness (column 24 line 67-column 25 line 3). One of ordinary skill in the art would have had a reasonable expectation of success because Nicotera teaches using protein kinase inhibitors to treat hearing loss in the same formats as Meijer and at the same dosage.

Therefore, the combined teachings of Meijer, Nicotera and Schaefer render obvious Applicant's invention as claimed.

Response to Arguments

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Schuberg whose telephone number is 571-272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651

Laura Schuberg